

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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THE UNITED STATES OF AMERICA *et al.*  
*ex rel.* JULIE LONG,

Plaintiffs,

v.

JANSSEN BIOTECH, INC.,

Defendant.

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Civil Action No. 16-CV-12182-FDS

**REDACTED DOCUMENT**

**PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF HER MOTION TO  
COMPEL DISCLOSURE OF ALL LEGAL OPINIONS AND ANALYSES  
RELATED TO THE LEGALITY OF THE INFUSION BUSINESS  
SUPPORT AND CONSULTATIVE SERVICES AT ISSUE**

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Plaintiff-relator Julie Long submits this memorandum of law in support of her motion under Federal Rules of Civil Procedure 26(b) and 37(a) requesting the Court to order Defendant Janssen Biotech, Inc., to produce all legal advice, opinions, reviews, and analyses related to the lawfulness of the infusion business support and consultative services at issue in this litigation or, in the alternative, prohibit Janssen from presenting any legal analyses or opinions, including any legal opinions it received from its Promotional Review Committee, to support any defense to Plaintiff's claims.

Plaintiff attempted in good faith to resolve this issue before seeking the Court's intervention. On several occasions, including during hearings before the Court, counsel for the parties have discussed the reliance upon counsel defense and waiver issues raised herein, but have been unable to reach a resolution.

## **I. FACTUAL BACKGROUND**

### **a. Plaintiff's Allegations**

In this action, Plaintiff alleges that, starting in approximately 2001, one of Janssen's main strategies for growing sales of Remicade and Simponi ARIA—two drugs administered via infusion—was to promote the infusion business model by helping rheumatology and gastroenterology practices open in-office infusion suites ("IOI") and, after an IOI was open, by influencing the physician practices to perform more infusion procedures. As part of this strategy, Janssen employed a large team of medical practice advisers to furnish free, ongoing operational support to physicians who were committed to the infusion business model and opened IOIs. Janssen called this special team of employees "Area Business Specialists," or "ABSs" for short. Janssen also paid business consultants with expertise in medical practice and infusion business

management, such as Xcenda and The Lash Group, to assist the physician practices with opening and operating IOIs.

Janssen had ABSs and outside consultants meet with physician practices that did not have an IOI and advise them to open an IOI to perform infusion procedures. If a physician practice was interested, Janssen then advised the practice on how to open and set up the IOI. Once open, Janssen wanted to make sure the IOIs remained open and that the physician practices grew the number of infusion procedures they performed in the IOIs. Janssen did all this to induce the physician practices to prescribe, purchase, and infuse more Remicade and Simponi ARIA.

The free practice management and infusion business advice and support that Janssen had ABSs and outside consultants regularly provide the physician practices covered a wide range of topics that fell within four general categories: (1) opening, designing, and setting-up an IOI; (2) growing the IOI and improving the IOI's efficiency and optimizing its infusion schedule; (3) managing the IOI business; and (4) managing relationships with insurance companies and negotiating higher reimbursement rates for regularly billed services and drugs. Janssen often referred to the practice management and infusion operations advice and support and the presentations it utilized in providing the advice and support as, among other things, "programs." These free business services and the related presentations and programs are collectively referred to herein as "IOI Support."

The IOI Support, which helped physicians open, operate, manage, and grow IOIs, where they infused a variety of infusible drugs, not just Remicade and Simponi ARIA, provided broad value to the physicians. Although the IOI Support applied to the overall infusion business and all infusible drugs, Janssen's purpose in providing these

services for free was to gain loyalty and induce sales and infusions of its products (Remicade and Simponi ARIA).

Plaintiff alleges that by providing the various types of valuable IOI Support to induce the physicians to prescribe and administer Remicade and Simponi ARIA infusions to their patients, many of whom are covered by Medicare, Janssen violated the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b, which prohibits “knowingly and willfully” soliciting, receiving, offering, or paying any “remuneration (including any kickback, bribe, or rebate) . . . to induce [a] person” to purchase, order, or recommend purchasing or ordering a good, service, or item “for which payment may be made in whole or in part under a Federal health care program.” 42 U.S.C. § 1320a-7b(b).

As a result, by providing the valuable IOI Support Janssen corrupted and tainted the recipient doctors’ treatment decisions and, accordingly, rendered the bills those physicians submitted to Medicare for Remicade and Simponi ARIA and the related infusion procedures false and ineligible for reimbursement under the False Claims Act (“FCA”).

#### **b. Both the AKS and FCA Require Proof of Defendant’s Scienter**

To succeed on her AKS and FCA claims, Plaintiff must show that Janssen acted “knowingly and willfully” in violation of the AKS. See 42 U.S.C. § 1320a-7b(b)(2). “To act knowingly, a defendant must ‘do something voluntarily . . . do it deliberately . . . not do something by mistake or accident or even negligently,’ and to act willfully, a defendant must ‘do something purposely, with the intent to violate the law . . . do something purposely that law forbids.’” *United States ex rel. Banigan v. Organon USA Inc.*, CV 07-12153-RWZ, 2016 WL 10704126, at \*3 (D. Mass. Aug. 23, 2016) (quoting *United States*

*v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F. 2d 20, 33 (1st Cir. 1989)).

Plaintiff must also show that Janssen acted knowingly in causing false claims to be presented to the United States for payment or approval, see 31 U.S.C. § 3729(a)(1), or that it acted knowingly by making, using, or causing to be made or used, a false record or statement to get—or that was material to—false or fraudulent claims paid or approved by the United States. See 31 U.S.C. § 3729(a)(2). Under the FCA, the term “knowingly” means that a person, with respect to information contained in a claim, (i) “has actual knowledge of the information”; (ii) “acts in deliberate ignorance of the truth or falsity of the information”; or (iii) “acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1).

### **c. Janssen’s Scienter-Related Defenses**

In its answer, Janssen denies that it “knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States.” See Answer, ECF No. 83 at ¶ 211. It further denies that it “knowingly made, used, or caused to be made or used, a false record to get, or that was material to, false or fraudulent claims paid or approved by the United States.” *Id.* at ¶ 218. Janssen then asserts affirmative defenses that specifically dispute the scienter elements of Plaintiff’s claims:

- Affirmative Defense 8—“Relator’s claims for relief are barred, in whole or in part, because any false claims that Janssen allegedly submitted or caused to be submitted and any false record or statement that Janssen allegedly made, used, or caused to be made or used to get a claim paid were not done knowingly.” *Id.* at p. 52.



- Affirmative Defense 13—“Relator’s claims for relief are barred, in whole or in part, because Janssen reasonably interpreted the statutes and regulations at issue in the SAC.” *Id.* at p. 52.
- Affirmative Defense 14—“Relator’s claims for relief are barred, in whole or in part, because any and all actions taken by Janssen with respect to any of the matters alleged by Relator were taken in good faith and in accordance with established industry practice.” *Id.* at p. 52.

Janssen has made clear through these affirmative defenses, as well as its responses to discovery and its statements to the Court, that it is putting forth the defense that it acted in good faith (*i.e.*, did not act “knowingly” or “knowingly and willfully”) because it reviewed the legality of the IOI Support as well as the written materials and presentations it utilized in providing the IOI Support and determined that providing them to physician practices was lawful. These defenses directly put at issue Janssen’s knowledge regarding the legality of its IOI Support, including all advice, opinions, reviews, and analyses it received or performed regarding the legality of the IOI Support, thereby waiving any privilege that might have otherwise protected this information from discovery.

That Janssen has put this information at issue in this case is demonstrated by arguments made by Janssen’s counsel at multiple hearings, including the October 1, 2021 hearing, asserting that the Court will be able to enter summary judgment against Plaintiff on the issue of scienter because Janssen put its IOI Support “through a top flight . . . Johnson & Johnson level promotional review committee.” Oct. 1, 2021 Hearing, ECF No. 186, at 24:17-22. Janssen summarized its position regarding Plaintiff’s challenges to the IOI Support as follows: “We don’t think they’re unlawful. We

don't think they're kickbacks. These were programs that were nationwide. They were reviewed and approved by the company's promotional review committee." *Id.* at 22:2-5.

This "top flight" promotional review committee ("PRC") that Janssen used to review the presentations and other written materials Janssen utilized in providing the various types of IOI Support included a lawyer who, according to Janssen, [REDACTED]

[REDACTED].<sup>1</sup>

Further, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].<sup>2</sup> When asked for the names of key persons "responsible for analyzing the lawfulness of providing any IOI Support, including providing any of the IOI Support Presentations," and the "Infusion Services Review . . . presentation, program, or consultative session to IOI Accounts," Janssen

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<sup>1</sup> See, e.g., Janssen's supplemental response to Interrogatory No. 3 asking for the names of "each Employee who reviewed or analyzed the lawfulness of helping physicians open an IOI," which was, in part, that its [REDACTED]

[REDACTED] Exhibit A, Janssen's Supplemental Objections and Responses to Plaintiff's First Set of Interrogatories (filed separately under seal), at pp. 10-11; Janssen's second supplemental response to Interrogatory No. 8 asking for the names of employees "responsible for reviewing or analyzing the lawfulness of providing the Infusion Services Review . . . presentation, program, or consultative session to IOI Accounts," which was, in part, that its [REDACTED]

[REDACTED] Exhibit B, Janssen's Second Supplemental Objections and Responses to Plaintiff's First Set of Interrogatories (filed separately under seal), at pp. 10-11.

<sup>2</sup> Exhibit B at pp. 15.

again asserted that [REDACTED]

<sup>3</sup>

Janssen's lawyers' substantial involvement in the PRC's reviews of written materials utilized in the field, including the various slide decks Janssen utilized in providing the IOI Support, is demonstrated by Janssen's standard operating procedures

[REDACTED] See,

e.g., Exhibit D, SOP-10234, at p. 4 (filed separately under seal). The legal representative on the PRC [REDACTED]

[REDACTED] *Id.* at p. 4. The legal representative may be [REDACTED]

[REDACTED] See Exhibit E, Approval of Promotional

Material for Therapeutic Products, at p. 2 ¶ 1 (filed separately under seal). All members of the PRC, including the legal representative, [REDACTED]

It should be noted that the PRC's function is limited to reviewing promotional materials, such as slide decks, printed pieces, and websites, before they can be used in the field, not to review the legality of business and marketing strategies. Although Janssen has produced documents showing that the PRC approved written

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<sup>3</sup> Exhibit C, Janssen's Responses to Plaintiff's May 19, 2021 Interrogatories (filed separately under seal), at pp. 13); Exhibit B at p. 11.

presentations and other materials that Janssen directed Plaintiff and other ABSs to utilize in providing the IOI Support, Janssen has not provided any discovery that indicates that the PRC provided legal advice concerning the legality of the overall strategy to regularly provide the various types of IOI Support to physician practices to induce physicians to prescribe and infuse Remicade and Simponi ARIA.

**d. Except for the PRC Approval Records, Janssen Is Withholding All Legal Analyses, Reviews, Advice, and Opinions Regarding the IOI Support as Attorney-Client Privileged**

The Court has repeatedly recognized that a key area of relevant discovery in this case is Janssen's assessment of the legality of the IOI Support. *See, e.g.*, Apr. 6, 2021 Hearing at 8:15-17 ("whoever devised these policies and vetted them and assessed their legality is going to be relevant at this stage"); *id.* at 16:3-8 ("she's entitled to find out from the company what was the policy, how did you vet it, what did you think about it, . . . are there internal documents discussing its legality that aren't privileged, and that type of thing. So I think you're just going to have to come up with those."); Apr. 23, 2021 Hearing at 25:10-15 ("The only nationwide information I think they're entitled to at this phase is what I talked about at the last hearing, which has to do with nationwide policymaking, the companies vetting those nationwide policies, the discussion of whether those nationwide policies are legal, in so far as those discussions are not privileged."); Dec. 20, 2021 Order (ECF No. 237) ("Janssen is ordered to provide discovery of legal advice Janssen received and any legal reviews or analyses Janssen performed or received, that are not privileged. The court orders Janssen to provide a privilege log concerning this information.").

To prove her claims and rebut Janssen's affirmative scienter-related defenses, Plaintiff has propounded discovery relevant to the issues of whether Janssen acted knowingly and willfully or with a true good faith belief that providing the IOI Support was lawful. Standing behind the shield of privilege, Janssen has objected to providing this relevant evidence—or even providing a privilege log for these withheld materials—despite its intention to use the PRC approvals, which are tantamount to legal opinions, as a sword to try to strike down Plaintiff's claims on the merits. While it has provided Plaintiff with reports from the PRC showing [REDACTED]

[REDACTED] Janssen is withholding the underlying legal analyses under a claim of privilege. See, e.g., Exhibit F, PRC Approval Form for Successful Implementation of a New Infusion Suite (filed separately under seal); Exhibit G, PRC Approval Form for Checkpoints for Infusion Center Optimization (filed separately under seal).

Plaintiff expressed to the Court the importance of discovery regarding legal opinions and analyses received by Janssen with regard to the IOI Support, arguing “one of the elements of a violation of a kickback statute claim is that the plaintiff is going to have to show that Janssen knew that providing these services was unlawful, and so discovery of advice it received from lawyers concerning whether it was lawful to provide these services is highly relevant.” (July 26, 2021 Hearing, ECF No. 157, at 7:15-20). At that time, the Court declined to require Janssen to produce such discovery because it was unknown whether Janssen would be raising an advice of counsel defense, without which, in the Court's opinion, many of the conversations regarding legal advice would be privileged. (*Id.* at 9:17-23). It then ordered Janssen to declare whether it will be relying on the advice of counsel as a defense. Order at ECF No. 205. While Janssen

has since denied that it will be doing so, it has confirmed that it will be relying on the PRC approvals, which required [REDACTED]

[REDACTED]. See Exhibit E at ¶ 3. In an attempt to have its cake and eat it too by not asserting an advice of counsel defense while still relying on its receipt of legal advice as part of its good faith defense, Janssen informed Plaintiff:

Outside of the narrow advice-of-counsel doctrine, Janssen reserves all of its rights to invoke and rely upon any and all other available arguments and defenses, including that Janssen followed a business practice of having a multi-disciplinary committee that included a lawyer review and approve the challenged presentations and resources.

Exhibit H, Dec. 21, 2021 Letter, at p. 1 (citations omitted).

Janssen's refusal to produce legal analyses and opinions underlying its decision to implement and continue the IOI Support on the basis of privilege is improper as Janssen has affirmatively put this matter at issue. The Court must reject Janssen's attempt to use the attorney-client privilege as both a sword and a shield by compelling it to disclose all legal analyses, reviews, advice, and opinions it received regarding the legality of the IOI Support from its legal department, outside counsel, and the lawyers on the PRC. Or, in the alternative, the Court should preclude Janssen from using the PRC approval records to support any defense.

## **II. ARGUMENT**

The Court should find that Janssen waived its attorney-client privilege with regard to any and all opinions and analyses of the legality of the IOI Support. In the alternative, the Court should prohibit Janssen from asserting any defense that is supported by such

legal analyses, advice, and opinions, including the use of the PRC approvals in support of a defense that it had a good faith belief that its IOI Support complied with the law.

**a. Janssen has waived the attorney-client privilege with regard to any analyses and opinions of the legality of the IOI Support**

“The attorney-client privilege ‘protects only those communications that are confidential and are made for the purpose of seeking or receiving legal advice.’” *Columbia Data Products, Inc. v. Autonomy Corp. Ltd.*, CIV.A. 11-12077-NMG, 2012 WL 6212898, at \*14 (D. Mass. Dec. 12, 2012) (quoting *In re Keeper of the Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 22 (1st Cir. 2003)). “The party invoking a recognized privilege has the burden of establishing, not only the existence of that privilege, but also that the established privilege was not waived.” *Id.* at \*11 (quoting *Cavallaro v. United States*, 153 F. Supp. 2d 52, 56 (D. Mass. 2001), *aff’d* 284 F.3d 236 (1st Cir. 2002)). Courts must narrowly construe the attorney-client privilege “because it comes with substantial costs and stands as an obstacle of sorts to the search for truth.” *In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 22 (1st Cir. 2003) (citing *United States v. Nixon*, 418 U.S. 683, 709–10 (1974)).

The attorney-client privilege may be waived expressly or by implication. *Id.* at 22-23. Here, Janssen’s conduct amounts to both an express and implied waiver of any attorney-client privilege with regard to legal opinions and analyses concerning the legality of providing the IOI Support.

**1. Janssen has Expressly Waived the Attorney-Client Privilege**

By its knowing and voluntary production of the PRC reports, which constitute legal opinions that the various written presentations and tools Janssen utilized in

providing the IOI Support to physician practices comply with applicable law, Janssen has expressly waived its privilege with regard to any documents and communications related to these legal opinions. See *Trustees of Boston Univ. v. Everlight Elecs. Co., Ltd.*, CIV.A. 12-11935-PBS, 2015 WL 3407555, at \*3 (D. Mass. May 27, 2015) (“Ordinarily, deliberate disclosure of a privileged communication, where no privilege protects this further disclosure, waives a communication privilege.”) (quoting *United States v. Rakes*, 136 F.3d 1, 5 (1st Cir. 1998)). Janssen’s express waiver extends not only to the legal analyses underlying the PRC approvals themselves, but also to all documents and communications on the subject of legality of providing the various types of IOI Support services and programs at issue. See *In re Lernout & Hauspie Sec. Litig.*, 222 F.R.D. 29, 35 (D. Mass. 2004) (holding knowing disclosure of attorney-client privileged material waives all communications on the same subject) (citing *Texaco Puerto Rico, Inc. v. Dep’t of Consumer Affairs*, 60 F.3d 867, 883-84 (1st Cir. 1995)); *AMCA Intern. Corp. v. Phipard*, 107 F.R.D. 39, 40-44 (D. Mass. 1985) (holding plaintiff’s release of a document from its attorney waived the attorney-client privilege as to documents relating to the same subject matter).

Federal Rule of Evidence 502 also requires Janssen’s express waiver of the attorney-client privilege be applied not only to the disclosed PRC reports themselves, but also to all documents and communications on the same subject matter. That Rule provides:

When the disclosure is made in a federal proceeding . . . and waives the attorney-client privilege or work-product protection, the waiver extends to an undisclosed communication or information in a federal or state proceeding only if:

(1) the waiver is intentional;



(2) the disclosed and undisclosed communications or information concern the same subject matter; and

(3) they ought in fairness to be considered together.

FRE 502(a). The Advisory Committee Notes explain the rule is drafted to apply to those situations in which “fairness requires a further disclosure of related, protected information, in order to prevent a selective and misleading presentation of evidence to the disadvantage of the adversary”. Notes to FRE 502(a). Under the rule, “a party that makes a selective, misleading presentation that is unfair to the adversary opens itself to a more complete and accurate presentation.” *Id.*; see also Statement of Congressional Intent, 154 Cong. Rec. H7818-7819, Sept. 8, 2008, 2008 WL 4133109 (rule addresses “when a party’s strategic use in litigation of otherwise privileged information obliges that party to waive the privilege regarding other information concerning the same subject matter so that the information can be fairly considered in context”).

Here, Janssen is attempting to use the PRC approvals as evidence that it determined providing the various IOI Support services and programs was legal prior to providing them to physician practices and, therefore, it could not have violated the AKS or FCA because its actions were in good faith and not knowingly and willfully in violation of the law. At the same time, it is invoking the attorney-client privilege in an effort to withhold from Plaintiff all other opinions, advice, reviews, and analyses of the legality of the IOI Support including all advice and opinions it received from its legal department as well as all legal reviews and evaluations that its attorneys performed. But, in fairness, this evidence ought to be considered together. See *In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 24 (1st Cir. 2003) (“subject matter waiver . . . ensures fairness because it disables litigants from using the attorney-

client privilege as both a sword and a shield[, preventing a party from] selectively disclos[ing] fragments helpful to its cause, entomb other (unhelpful) fragments, and in that way kidnap the truth-seeking process”). Without this evidence, Plaintiff will be unable to ascertain what legal advice Janssen received, whether full disclosure was provided to the attorneys who provided the advice, the reasonableness of the advice, and whether it actually followed that legal advice, and both the Court and the jury will be unable to fully assess the merits of Janssen’s good faith defense. The Court must, therefore, compel Janssen to disclose all documents and communications on the subject matter of the legality of providing the IOI Support.

## **2. Janssen has Impliedly Waived the Attorney-Client Privilege**

Janssen has also impliedly waived the attorney-client privilege with regard to all opinions, advice, reviews, and analyses concerning the legality of the IOI Support. “An implied waiver occurs when the party asserting the privilege places protected information at issue for personal benefit through some affirmative act, and to protect against disclosure of that information would be unfair to the opposing party.” *Traverse v. Gutierrez Co.*, CV 18-10175-DJC, 2019 WL 12291347, at \*6 (D. Mass. May 6, 2019) (citing *In re Keeper of the Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 24 (1st Cir. 2003)).

“Generally, courts use a three-factor test in determining whether an at-issue waiver has occurred: (1) whether the proponent of the privilege took some affirmative step such as filing a pleading; (2) whether the affirmative act put the privileged information at issue by making it relevant to the case; and (3) whether upholding the privilege would deny the opposing party access to information vital to its case.” *Id.*

(citing *Bacchi v. Massachusetts Mut. Life Ins. Co.*, 110 F. Supp. 3d 270, 276 (D. Mass. 2015)). Some courts add a reliance prong that requires the party's claim or defense "rel[y] on certain facts that can only be tested or rebutted if the adversary is given access to the privileged material." *Bacchi* at 276 (citing *In re County of Erie*, 546 F.3d 222, 229 (2d Cir. 2008)). "[I]f the defendant were to raise the defense that it acted based on its own subjective good faith belief that its actions were lawful, then the reliance element would likely be met, and that is so even if the defendant were to state that it did not intend to introduce any evidence regarding its attorneys' advice." *Id.* (citing *Erie* at 228). "That is because the plaintiff, in order to test the assertion of good faith, would need to know whether the defendant received any legal advice suggesting that its actions were in fact not lawful." *Id.* (citing *Erie* at 228).<sup>4</sup>

Here, Janssen has put forth affirmative defenses that it acted based on its own subjective good faith belief that its actions were lawful and is relying upon legal opinions (*i.e.*, the PRC approvals) to support its defenses. In order for Plaintiff to test Janssen's

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<sup>4</sup> See also, *e.g.*, *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991) (defendant's "testimony that he thought his actions were legal would have put his knowledge of the law and the basis for his understanding of what the law required in issue. His conversations with counsel regarding the legality of his schemes would have been directly relevant in determining the extent of his knowledge and, as a result, his intent."); *Cox v. Adm'r U.S. Steel & Carnegie*, 17 F.3d 1386, 1419 (11th Cir. 1994) ("Having gone beyond mere denial, affirmatively to assert good faith, [defendant] injected the issue of its knowledge of the law into the case and thereby waived the attorney-client privilege."); *United States v. Ormat Indus., Ltd.*, 314CV00325RCJVPC, 2016 WL 4107682, at \*4 (D. Nev. Aug. 1, 2016) (holding defendant's affirmative defenses, including defense of good faith, went "beyond mere denial of scienter to put its state of mind and knowledge of the [statutory] requirements at issue" resulting in waiver of privilege over attorney-client communications); *Hamilton v. Yavapai Cmty. Coll. Dist.*, CV-12-08193-PCT-GMS, 2016 WL 8199695, at \*2 (D. Ariz. June 29, 2016) ("where the Defendants assert their subjective good faith with respect to a matter of legal compliance, as the Defendants do here, a determination of such subjective good faith may depend on the advice given the Defendants by their counsel" and result in waiver of the attorney-client privilege).

assertion of good faith, it needs to know whether Janssen received any legal advice suggesting or warning that providing the IOI Support may not be lawful. See *id.* It would be fundamentally unfair to allow Janssen to disclose and argue it only relied on the PRC approvals/legal opinions while simultaneously concealing the analyses underlying those opinions and other legal advice, opinions and analyses that Janssen has received regarding the legality of the various IOI Support services and programs at issue. See *Saint-Gobain/Norton Indus. Ceramics Corp. v. Gen. Elec. Co.*, 884 F. Supp. 31, 33 (D. Mass. 1995) (“[I]t would be fundamentally unfair to allow a party to disclose opinions which support its position, and simultaneously conceal those which are adverse.”).

“[O]nce a litigant puts the legal advice given to him at issue, the opposing party should be entitled to all the information on that same subject regardless of when it was compiled. This ensures that a litigant is not able to present only selected bits of the story and thus distort the truth-seeking process.” *In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 26 (1st Cir. 2003); see also *Fonar Corp. v. Johnson & Johnson*, CIV.A. 82-2751-K, 1985 WL 186693, at \*2 (D. Mass. Aug. 20, 1985) (where “the advice of counsel has been put in issue, all advisory opinions on the same matter may need be discoverable if the evils of ‘opinion shopping’ and selective disclosure are to be avoided”) (citations omitted). As Janssen has put the legal advice given to it at issue, it should likewise be found to have waived any privilege as to all information on the same subject, *i.e.*, all documents and communications setting forth advice, opinions, reviews, and analyses regarding the legality of providing the IOI Support to physician practices.

**b. Janssen's Denial that it is Relying on the Advice of Counsel is Not Controlling**

In an effort to avoid disclosing the legal opinions and analyses it relied on (or ignored), Janssen has advised Plaintiff and the Court that it will not be invoking the advice of counsel defense. But Janssen's denial, which is belied by its affirmative defenses and its representations to Plaintiff and the Court regarding its reliance upon the PRC approvals/legal opinions, is not controlling.

This Court explained in *United States v. Gorski*, 36 F. Supp. 3d 256, 268 (D. Mass. 2014) (Saylor, J.):

[E]ither a formal advice-of-counsel defense or a more basic lack-of-*mens-rea* defense—a defendant's decision to raise the advice or involvement of counsel may serve as a waiver of the attorney-client privilege. That rule is premised on notions of basic fairness and common sense. Put simply, a defendant cannot have it both ways; he cannot claim he relied in good faith on the advice of counsel while using the privilege to prevent inquiry into the nature of his interactions with that counsel. *See In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 24 (1st Cir. 2003) (noting that the assertion of an advice-of-counsel defense waives the attorney-client privilege between the defendant and the attorney whose advice he or she relied on; “[w]ere the law otherwise, the client could selectively disclose fragments helpful to its cause, entomb other (unhelpful) fragments, and in that way kidnap the truth-seeking process.”); *see also* 1 McCormick On Evid. § 93 (7th ed.) (in actions where “a party interjects that the ‘advice of counsel’ as an essential element of a claim or defense, then that party waives the privilege as to all advice received concerning the same subject matter.”). Nor can he engage in selective disclosure, revealing some communications and claiming the privilege as to others. *In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d at 24.

The Court further explained that whether a party's reference to counsel is sufficient to waive the privilege is based on the facts and circumstances of the case and considered under the concept of fairness:

Not every passing reference to counsel will, however, trigger a waiver of the privilege. *See, e.g., United States v. White*, 887 F.2d 267, 271 (D.C. Cir. 1989) (“A general assertion lacking substantive content that one's attorney has examined a certain matter is not sufficient to waive the attorney-client

privilege.”). Whether such a waiver is triggered necessarily depends on the facts and circumstances of the case. *See In re Grand Jury Proceedings*, 219 F.3d 175, 187–90 (2d Cir. 2000). The touchstone is fairness; a defendant cannot put his attorney's advice or involvement at issue in a case and then claim a privilege as to the details of that advice or involvement.

*Id.*

In *Diamond Staffing Sols., Inc. v. Diamond Staffing, Inc.*, 05-40046-FDS, 2005 WL 8176474 (D. Mass. July 8, 2005) (Saylor, J.), the Court applied these principles when holding the defendant had waived attorney-client privilege by placing the reliance on the advice of counsel at issue despite representing that it was not raising an advice of counsel defense. There, plaintiff sued the defendant for infringing its service mark. *Id.* at \*1. The defendant denied that it was asserting an advice of counsel defense, but it put forth evidence and argument that it conferred with its attorney before selecting its name and the attorney investigated and signed off on the name selection. *Id.* at \*2-3. Plaintiff deposed the attorney who refused to answer questions regarding direct communications of legal advice she had with the defendant. *Id.* at \*2. The Court held the defendant waived any privilege by putting the advice of counsel in issue:

There is no question that [defendant's] intent in adopting its corporate name is relevant to [plaintiff's] likelihood of success of establishing trademark infringement. *See, e.g., Boustany v. Boston Dental Group, Inc.*, 42 F. Supp. 2d 100, 108 (D. Mass. 1999) (listing the eight factors a court must consider to determine whether there is a likelihood of confusion of two marks). . . . If [defendant] simply denied the allegation of bad-faith intent, [its attorney's] advice would not have been placed at issue. But [defendant] went further and affirmatively offered—through, among other things, the affidavits submitted in support of its dispositive motion—proof of [defendant's] reliance on [its attorney's] advice to rebut [plaintiff's] allegation of bad-faith intent. Therefore, it was [defendant] who placed reliance on the advice of counsel at issue, and [defendant] must be deemed to have waived the privilege for communications between [its attorney] and her client relating to the claimed reliance. *See generally* Paul R. Rice, Attorney-Client Privilege in the United States, § 9:44 (2d ed. 2005) (collecting cases).

[Defendant] cannot at the same time cloak itself in consultation with counsel as evidence of its good faith, yet prevent [plaintiff] from discovering the contents of the communications. *See In re Keeper of the Records*, 348 F.3d 16, 24 (1st Cir. 2003). Regardless of whether [defendant] has asserted the advice of counsel as an affirmative defense under Fed. R. Civ. P. 8(c), a fair reading of its submissions to the Court thus far establishes that [defendant] has indicated that it intends to rely on advice of counsel.

*Id.* at \*3.

Just as the defendant did in *Diamond Staffing*, Janssen has indicated through its actions—its statements to the Court and to Plaintiff and its assertion of affirmative defenses—that it intends to rely on the advice of counsel despite stating that it does not intend to raise a formal advice of counsel defense. Because it would be unfair to allow Janssen to “cloak itself in consultation with counsel [on the PRC] as evidence of its good faith, yet prevent [Plaintiff] from discovering the contents of the communications,” *id.*, the Court must reject Janssen’s efforts to withhold the legal advice, opinions, reviews, and analyses it received or performed merely by asserting that it is not mounting a formal advice of counsel defense.

**c. Alternatively, the Court should Prohibit Janssen from Asserting any Defense that is Supported by Analyses, Advice or Opinions Regarding the Legality of the IOI Support, Including Prohibiting the Use of the PRC Approvals**

In the alternative, Plaintiff requests that the Court enter an order prohibiting Janssen from asserting any defense that is supported by such legal analyses and opinions, including the use of the PRC approvals in support of an affirmative defense that it had a good faith belief that providing physicians the IOI Support complied with the law. This Court has recognized that “the party claiming the advice of counsel has a tough choice: claim the defense or claim the attorney-client privilege.” *Diamond Staffing* at \*4 (quoting *Mushroom Assocs. v. Monterrey Mushrooms, Inc.*, No. C-91-1092 THE

(PJH), 1992 WL 442892, \*3 (N.D. Cal. May 19, 1992)). If the Court finds Janssen has maintained its ability to claim the attorney-client privilege, then it should hold that Janssen is not able to also rely on any defense that is supported by analyses and opinions regarding the legality of the IOI Support, including relying on PRC approvals as part of its good faith defense.

### **III. CONCLUSION**

Despite Janssen's claim that it is not raising a formal advice of counsel defense, it has made its reliance on counsel's advice an issue in this action by raising affirmative defenses that claim it acted in good faith (*i.e.*, not knowingly and willfully) when providing the IOI Support because the various presentations utilized in providing several types of IOI Support were approved by its PRC, which included an attorney who determined the presentations to be in compliance with the applicable law. Janssen has thwarted Plaintiff's ability to assess this good faith defense or even verify that Janssen received and followed legal advice that each IOI Support presentation complied with the AKS and FCA because Janssen has raised the attorney-client privilege to withhold all legal opinions and analyses. This has created a patently unfair situation in which Janssen is using the attorney-client privilege as both a sword and a shield in order to deny Plaintiff access to crucial evidence. The Court should hold that Janssen has waived any privilege with regard to all legal analyses underlying the PRC approvals and all legal opinions, advice, reviews, and analyses its legal department or outside counsel provided or performed concerning the legality of providing the IOI Support and order their production. In the alternative, the Court should prohibit Janssen from using the PRC approvals to support any defense to Plaintiff's claims.



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Respectfully submitted,

/s/ Theodore J. Leopold

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**CERTIFICATE OF SERVICE**

I hereby certify that on January 28, 2022, this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

s/ Theodore J. Leopold  
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